IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
CLARKSBURG DIVISION

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. MYLAN PHARMACEUTICALS INC., Defendant.	Case No. 1:22-cv-00061-TSK **JURY TRIAL DEMANDED**

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF
REGENERON'S MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

OTHER AUTHORITIES

Mylan asserts as obviousness references Regeneron's own patent and patent applications, in plain violation of 35 U.S.C. § 103(c). The Court should decline Mylan's invitation to ignore the clear language of the statute and controlling precedent interpreting it.

The Patent Act precludes patenting subject matter that "as a whole would have been obvious at the time the invention was made." 35 U.S.C. § 103(a). But that provision has an important exception. Under 35 U.S.C. § 103(c), Congress provided that certain prior art "shall not preclude patentability under [§ 103] where the [prior art] and the claimed invention were, at the time the claimed invention was made, *owned by the same person or subject to an obligation of assignment to the same person*." Mylan and its expert, Dr. Barrett Rabinow, however, have argued that Regeneron's asserted U.S. Patent 11,084,865 (the "'865 patent"), directed to ophthalmic formulations of aflibercept, is obvious over other patents and patent applications owned by Regeneron, including U.S. Patents 8,110,546 ("Dix '546") and 10,406,226 ("Dix '226"), and international patent application WO2006/088650 ("Wiegand"). These references may not be considered in an obviousness analysis under § 103(c), and the Court should thus enter partial summary judgment of nonobviousness.

I. Background

A. Statutory Framework

35 U.S.C. § 103(c)(1) provides:

> (1) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102, shall not preclude patentability under this section where the subject matter and the claimed invention were, *at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person*.

"It is historically very clear that this provision was intended to avoid the invalidation of patents under § 103 on the basis of the work of fellow employees engaged in team research." *OddzOn*

Prods., Inc. v. Just Toys, Inc., 122 F.3d 1396, 1403 (Fed. Cir. 1997) (citing *Section–by–Section Analysis: Patent Law Amendments Act of 1984*, 130 Cong. Rec. 28069, 28071 (Oct. 1, 1984), *reprinted in* 1984 U.S.C.C.A.N. 5827, 5833 (stating that the amendment encourages communication among members of research teams)).

Congress amended § 103(c) in the American Inventor Protection Act to confirm its applicability to prior art under § 102(e), and that version of the statute applies to "patents filed on or after the November 29, 1999 effective date." *Riverwood Int'l Corp. v. R.A. Jones & Co., Inc.*, 324 F.3d 1346, 1355 n.2 (Fed. Cir. 2003) (citing American Inventors Protection Act, Pub. L. 106–113, 113 Stat. 1536, 1501A–591 (1999)). That is the version that governs here: the '865 patent indisputably has an effective filing date no later than June 16, 2006. Ex. 1 (Rabinow Opening Report) ¶ 61 (applying the priority date of June 16, 2006); Ex. 2 (Trout Responsive Report) ¶ 48 (priority date is no later than June 16, 2006).[1]

B. Mylan and Dr. Rabinow Rely on Dix '546, Dix '226, and Wiegand for Obviousness

Mylan has asserted the defense of obviousness against the '865 patent and purports to rely on three Regeneron patents or patent applications as prior art references: Dix '546, Dix '226, and Wiegand. Ex. 3 (Final Invalidity Contentions) at 162 (citing Dix '546); *id.* at 165 (citing Dix '226); *id.* at 163 (citing Wiegand). Each of these patents or applications was filed by and assigned to Regeneron Pharmaceuticals, Inc. Dix '546 and Dix '226 are United States patents assigned to Regeneron Pharmaceuticals, Inc. Ex. 4 (Dix '546), Ex. 5 (Dix '226). The patents are related and

[1] Congress later substantially revised § 103, in the America Invents Act. However, the America Invents Act applies only to patents with an effective filing date after March 16, 2013, and thus indisputably does not govern the '865 patent. *See, e.g.*, *Amerigen Pharm. Ltd. v. UCB Pharma GmbH*, 913 F.3d 1076, 1086 n.16 (Fed. Cir. 2019). However, the America Invents Act does apply to another asserted patent in this case, U.S. Patent 11,104,715 (relating to methods of manufacturing aflibercept), which has an effective filing date after March 16, 2013.

both name the Regeneron scientists Daniel Dix, Kelly Frye, and Susan Kautz as inventors. *Id.* Wiegand is an international patent application publication also filed by Regeneron Pharmaceuticals, Inc., with Regeneron scientists Stanley Wiegand and Jingtai Cao as named inventors. Ex. 6. And the '865 patent asserted in this case, of course, is also owned by Regeneron. Pursuant to their employment agreements with Regeneron, the inventors of named on each of these patent filings were under an obligation to assign their inventions to Regeneron, which is the reason that the '865 patent and the other references at issue were assigned to, and are owned by, Regeneron. *See, e.g.*, Ex. 7 ('865 Patent Assignment); Ex. 8 (Employment Agreement of Eric Furfine).

None of the references at issue were patented or published before the '865 patent's latest possible priority date of June 16, 2006, making them per se ineligible as prior art under any section other than 102(e). Dix '546 issued years later on February 7, 2012, and the application published July 13, 2010. Ex. 4; Ex. 9 (Mylan Invalidity Contentions Appx. B) at 20 ("Dix issued February 7, 2012" and "purports to be assigned to Regeneron Pharmaceuticals, Inc."). Likewise, Dix '226 issued on September 10, 2019, and the application published on December 21, 2017. Ex. 5; Ex. 9 at 36 ("The '226 patent issued September 10, 2019" and "purports to be assigned to Regeneron Pharmaceuticals, Inc."). Wiegand published on August 24, 2006, over two months after the latest possible priority date for the '865 patent. Ex. 6; Ex. 9 at 97 ("Wiegand published on August 24, 2006."). Mylan thus has asserted that these references are prior art for its obviousness arguments under § 102(e), not § 102(a) or § 102(b). Ex. 1 (Rabinow Opening Report) ¶¶ 122, 128, 170.

In view of the plain language of § 103(c) and to avoid burdening the Court with additional filings, last week Regeneron requested that Mylan withdraw its obviousness arguments referring to Dix '546, Dix '226, and Wiegand. Ex. 10 (Apr. 12, 2023 Email from A. Trask). Mylan declined

to respond.

II. Legal Standard

"The evidentiary burden to show facts supporting a conclusion of invalidity is one of clear and convincing evidence." *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 993-94 (Fed. Cir. 2009); *see also Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011); *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1068-69 (Fed. Cir. 2012).

Summary judgment is warranted where "no material facts are in dispute" after viewing the evidence in the light most favorable to the nonmoving party. *Carlson v. Bos. Sci. Corp.*, 856 F.3d 320, 324 (4th Cir. 2017); *accord Eli Lilly & Co. v. Hospira, Inc.*, 933 F.3d 1320, 1327 (Fed. Cir. 2019). Where, as here, the non-moving party bears the burden of proof, it must come forward with evidence sufficient to create a dispute, and must specifically cite such evidence in the record. *Carlson*, 856 F.3d at 324–25. "[T]here is no genuine issue if the evidence presented in the opposing affidavits is of insufficient caliber or quantity to allow a rational finder of fact to find [invalidity] by clear and convincing evidence." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 254 (1986).

III. Argument

Regeneron is entitled to partial summary judgment of nonobviousness because Mylan's obviousness arguments, which rely extensively on the references Dix '546, Dix '226, and Wiegand, are foreclosed by the unambiguous terms of 35 U.S.C. § 103(c). Ex. 1 (Rabinow Opening Report) ¶¶ 260-62, 266-67, 278-81, 289-90 (relying on Dix '226 and/or Dix '546); *id.* ¶ 280 (relying on Wiegand); Ex. 11 (Rabinow Reply Report) ¶¶ 90, 94-95, 112, 115, 119-20 (relying on Dix '226 and/or Dix '546). The three references are only asserted as prior art (and could only be prior art) under 35 U.S.C. § 102(e), and they always have been owned by Regeneron. Section 103(c) thus applies, and the references may not be considered in an obviousness analysis.

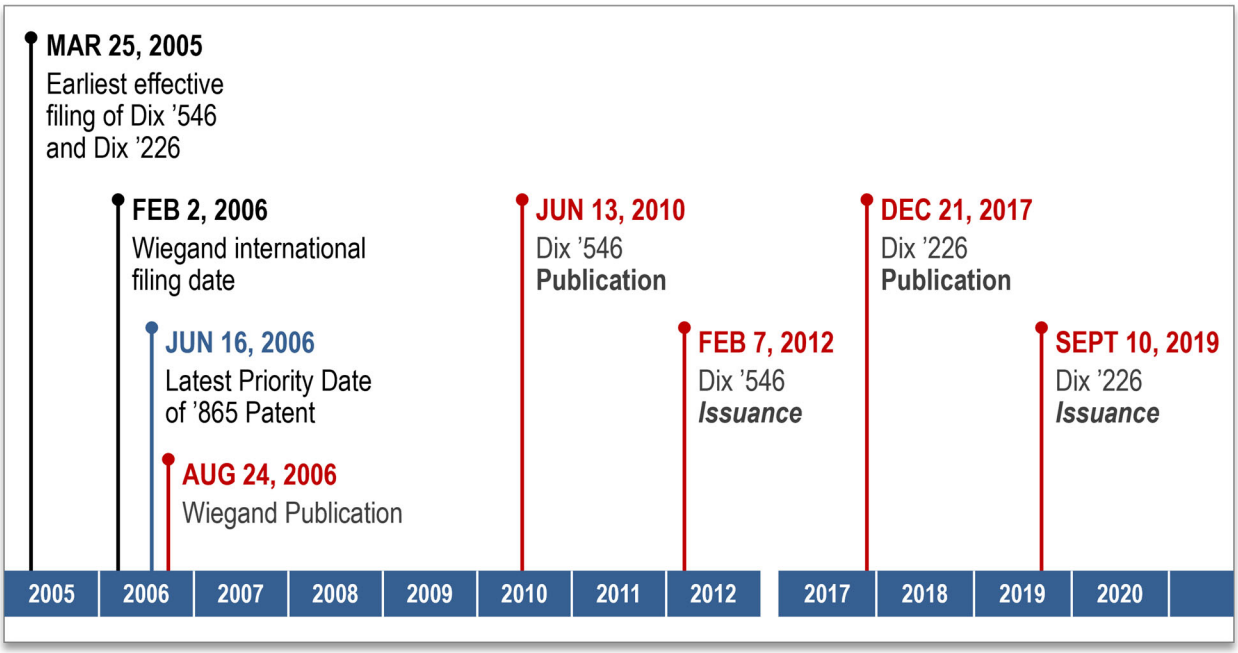
Because Mylan relies heavily on the Dix references in particular, resolution of this summary judgment motion would substantially simplify the issues for trial. Mylan, through Dr. Rabinow, asserts Dix '226 both as a discrete obviousness ground, Ex. 1 (Rabinow Opening Report) ¶¶ 279-81, and in combination with several other references, *e.g.*, *id.* ¶¶ 260, 262, 267, 289. Indeed, all but one of Mylan's obviousness grounds rely in whole or in part on the Dix references. And Mylan also relies on Wiegand for obviousness. *Id.* ¶ 280. While Mylan raises other invalidity arguments, including under § 102 and § 112, that are not at issue here, the Court should enter summary judgment of nonobviousness with respect to the three references relied on by Mylan whose teachings are foreclosed by the plain terms of § 103(c).

The references could only be prior art under 35 U.S.C. § 102(e). As relevant to the context here in § 103(c), Dix '546, Dix '226, and Wiegand undisputedly could only be prior art under 35 U.S.C. § 102(e). The references did not publish or issue as patents before the '865 patent's priority date, foreclosing application of 35 U.S.C. § 102(a) or § 102(b).[2] Mylan thus asserts only that they are prior art under § 102(e), which makes certain patents and published patent applications prior art based on their date of filing and before they are available to the public.[3] Ex. 1 (Rabinow Opening Report) ¶¶ 122, 128, 170. But prior art under that subsection falls within the prohibition in § 103(c), per that provision's plain terms. *See* 35 U.S.C. § 103(c) (barring

[2] 35 U.S.C. § 102(d) indisputably does not apply either. That provision concerns subject matter patented or caused to be patented "*in a foreign country*," but Dix '546 and Dix '226 are both United States patents, while Wiegand is a publication of an international patent application (not a patent).

[3] 35 U.S.C. § 102(e) reads: "A person shall be entitled to a patent unless — (e) the invention was described in — (1) *an application for patent, published under section 122(b)*, by another filed in the United States before the invention by the applicant for patent or (2) *a patent* granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language."

consideration of "[s]ubject matter developed by another person, which qualifies as prior art only under one or more of *subsections (e)*, (f), and (g) of section 102"). Mylan has not argued to the contrary, nor could it. The timeline below illustrates that the pertinent references did not publish or issue until after the latest possible priority date of the '865 patent:



The references have always been owned by Regeneron. Furthermore, "at the time the claimed invention was made," "the subject matter and the claimed invention were . . . owned by the same person or subject to an obligation of assignment to the same person," 35 U.S.C. § 103(c), i.e., Regeneron. Each of the references on its face identifies the assignee or applicant as Regeneron. And when filed, the references and the '865 patent were assigned by the inventors—all Regeneron scientists—to Regeneron Pharmaceuticals, Inc., pursuant to the inventors' employment agreements with Regeneron obligating them to assign their inventions to their employer. Ex. 12 (Dix '226 and '546 Assignment); Ex. 13 (Wiegand Assignment); Ex. 7 ('865 patent assignment); *e.g.*, Ex. 8 (Furfine Employment Agreement). Again, Mylan does not and cannot dispute this.

Section 103(c) bars consideration of the references for obviousness. For commonly-owned references, like these, that could only be prior art under § 102(e), the command of 35 U.S.C. § 103(c) is clear: such references "*shall not preclude patentability* under this section." *OddzOn*, 122 F.3d at 1403. Mylan's attempt to use the "work of fellow [Regeneron] employees engaged in team research" to invalidate other Regeneron patents is precisely the scenario § 103(c) was designed to foreclose. *Id.* (citing 1984 U.S.C.C.A.N. 5827, 5833); *see also Thomson, S.A. v. Quixote Corp.*, 166 F.3d 1172, 1175 n.3 (Fed. Cir. 1999). Under § 103(c), Mylan thus cannot rely on Dix '546, Dix '226, or Wiegand for its obviousness arguments, for any purpose that would "preclude patentability" under § 103. Accordingly, summary judgment of nonobviousness is warranted with respect to Mylan's obviousness arguments that purport to rely on any of these references in any way.

CONCLUSION

For the foregoing reasons, Regeneron is entitled to summary judgment of nonobviousness of the '865 patent under each of Mylan's § 103 defenses that rely on the teachings of Dix '546, Dix '226, and/or Wiegand.

Date: April 20, 2023

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CERTIFICATE OF SERVICE

I hereby certify that on April 20, 2023, I electronically filed the foregoing with the Clerk of the Court by using the Court's CM/ECF system. Counsel of record for all parties will be served by the Court's CM/ECF system.

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